

REASONS FOR PRE-APPEAL BRIEF REQUEST FOR REVIEW

Appellant has carefully reviewed the Final Office Action of June 8, 2010 and the Advisory Action of August 18, 2010. Currently, claims 22-38, 42, 43, and 45-47 remain pending of which claims 34-38, 43, and 45-47 were previously withdrawn with traverse. Claims 22-33 and 42 have been rejected by the Examiner.

Appellant hereby requests a pre-appeal conference and file this pre-appeal conference brief concurrently with a Notice of Appeal. Favorable consideration of the claims is respectfully requested.

Claims 22-33 and 42 were finally rejected under 35 U.S.C. 112, first paragraph. It is believed that the disclosure of forming a surfactant surface coating on a preformed cross-linked gelatin foam composition by briefly soaking the preformed cross-linked gelatin foam composition in a non-aqueous isopropanol solution of the wetting agent is described in Example 2 beginning at page 18 as discussed in detail in the paper of August 3, 2010. The Examiner no longer lists that rejection in the Advisory Action and it is believed that the rejection has been effectively overcome and should be overruled.

Claims 22-25, 27-30, 32, 33, and 42 were rejected under 35 U.S.C. 102(b) as anticipated by Pawelchak et al. (U.S. Patent No. 4,292,972). Pawelchak teaches a lyophilized foam sponge product formed from hydrocolloids, gelatin, pectin, and sodium carboxymethyl cellulose. The product is formed by forming an aqueous colloidal dispersion of hydrocolloids, aerating or foaming, freezing, and lyophilizing. (Abstract) Attention is directed to the lack of cross-linking, a non-aqueous solvent system, and a wetting agent in the initial disclosure. Pawelchak discloses that a surface tension modifier may be “added to the colloidal dispersion to stabilize the gas suspension and enhance the quality of the foam”. (“Col. 4, lines 47-52.”) The foamed or aerated colloidal dispersion, with any added surface tension modifier uniformly dispersed therein, is then poured into containers and frozen. At this point, the foam is an aqueous composition and is not cross-linked. The surface tension modifier, if present is uniformly dispersed throughout the resulting foam product rather than being present as a coating on the surface of a preformed gelatin sponge. Following lyophilization, “The lyophilized hydrocolloid foam product can be cross-linked so as to reduce its solubility and absorbability.” (Col. 5, lines 17-19.) It is disclosed

that the crosslinking agent may be added to the aerated or foamed colloidal dispersion which optionally may contain a surface tension modifier uniformly dispersed therein. In the alternative, the freeze dried lyophilized colloidal dispersion which optionally may contain a surface tension modifier may be exposed to formaldehyde or glutaraldehyde vapor or ultraviolet vapor. (Col. 5, lines 24-27.) Pawelchak does not disclose the addition of a wetting agent to a preformed crosslinked gelatin sponge from a non-aqueous solvent as a step in the foam sponge preparation process.

Applicant has carefully reviewed the Examples provided by Pawelchak for departures from the described foam sponge preparation process. Example 1 has no surface tension modifier and is not crosslinked. Example 2 has no surface tension modifier and is not crosslinked, although it “can be sterilized by exposure to gamma radiation at 1.5 Mrads”. There is no assertion that such exposure crosslinks the foam sponge or that it is subsequently treated with a crosslinking agent or surface tension modifier. Example 3 was prepared in the manner of Example 2 and has no surface tension modifier and is not crosslinked. Example 4 was prepared in the manner of Example 2 and has no surface tension modifier and is not crosslinked. Examples 5-20 were prepared in the manner of Examples 1 or 2 and have no surface tension modifier and are not crosslinked. Example 21 was prepared in the manner of Example 3, but with the addition of formaldehyde in water to the aerating foam prior to freezing and lyophilizing which is said to cross-link one or more of the (unspecified) hydrocolloids; however no surface tension modifier was added before or after freezing and lyophilizing. Example 22 teaches the addition of lyophilized thrombin to the composition of Example 1 prior to foaming and thus has no surface tension modifier and is not crosslinked. Example 23 describes the evaluation of the “hemostatic and bioabsorbability of a sponge product of the invention as compared with the commercially available product Gelfoam® (Upjohn)”. The material compared was that of Example 1 which again has no surface tension modifier and is not crosslinked.

Accordingly, Pawelchak does not disclose “a preformed cross-linked gelatin sponge; and a wetting agent; wherein the wetting agent decreases hydration time of the gelatin sponge and the wetting agent is soluble in a non-aqueous solvent; wherein the wetting agent is coated on at least a substantial portion of the surface of the preformed gelatin sponge by soaking the preformed gelatin sponge in a coating solution including the wetting agent and the non-aqueous solvent”, as recited in independent claim 22. No preformed crosslinked sponge of Pawelchak is coated by

exposing it to a non-aqueous solution of a wetting agent which is soluble in a non-aqueous solvent. There is no indication that a surface coating is structurally equivalent to a material uniformly dispersed within a sponge and it would not be understood to be equivalent by one of ordinary skill in the art. The Examiner clearly errs in asserting that the composition is anticipated because it contains similar components without properly taking into account that the materials of Pawelchak are not arranged as required by the claim.

As illustrated in the experimental section of the pending application and noted in the paper of August 3, 2010, the wetting agent Tween 60, specifically cited in the disclosure of Pawelchak, causes premature foam collapse (Table 5) when incorporated directly into the foaming composition under conditions taught by the pending application; however when coated onto the surface of a preformed sponge, deposition from a non-aqueous solvent does not significantly collapse the preformed and crosslinked foam and provides the benefit of reducing hydration time from 6 minutes to 24-35 seconds – a hydration time reduction of 90-93% with a wetting agent which was not otherwise usable in the sponge producing process of Correll.

At no time does the process described by Pawelchak involve a non-aqueous solvent and thus the sponge of Pawelchak, with or without a dispersed surface tension modifier therein, does not disclose a sponge having a coating deposited on the surface of a sponge from a non-aqueous solvent. Pawelchak does not disclose that a surface tension modifier, added “to stabilize the gas suspension and enhance the quality of the foam”, has any effect on the hydration time of a sponge when incorporated uniformly throughout the sponge as opposed to being present as a surface coating. Pawelchak fails to describe each and every element as set forth in the claim and the invention is not shown in as complete detail as is contained in the claim. Appellant respectfully requests that the rejection of claim 22 be overruled.

Claims 23-33 and 42, which depend from claim 22, and include significant additional limitations, are believed to be not anticipated by Pawelchak and Applicant respectfully requests that the rejections be overruled.

With regard to the rejections of claims 26 and 31 over Pawelchak in view of Yasushi et al. (JP 02-182259) and Song et al. (identified as EP 5568 334 (‘334), but believed to be EP 0 568 334), respectively, the Advisory Action notes that “Yasushi is relied upon for the solely [*sic*]


teaching of specific wetting agents as claimed by claim 26 and Song is relied upon for the solely [sic] teaching of inclusion of growth factor in wound dressing as claimed by claim 31". Accordingly, neither Yasushi nor Song overcomes the deficiencies of Pawelchak as applied to independent claim 22 which does not include those limitations. Claims 26 and 31, which depend from nonobvious independent claim 22, are also believed to be nonobvious and Appellant respectfully requests that the rejections be overruled.

For at least the reasons mentioned above, all of the pending claims are allowable over the cited prior art. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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Glenn M. Seager, Reg. No. 36,926
CROMPTON, SEAGER & TUFTE, LLC
1221 Nicollet Avenue, Suite 800
Minneapolis, Minnesota 55403-2420
Tel: (612) 677-9050